

RECEIVED
CENTRAL FAX CENTER

FEB 26 2007

6

Serial No. 10/814,660
Docket No. 00802-22708

REMARKS

Applicants thank the Examiner for consideration of the subject patent application. In the office action mailed December 27, 2006, Claims 1-27 were pending for consideration. Claims 2, 4-6, 25, and 26 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Claims 1-13 and 15-27 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. 4,482,538 (hereinafter "Davies") in view of the article, *Ultradispersivity of Diamond at the Nanoscale* (hereinafter "Raty"). Additionally, Claim 14 was rejected as allegedly obvious over Davies and Raty further in view of *Cosmetics Additives: An Industrial Guide* (hereinafter "Flick"). Each of these rejections will be addressed in turn below.

By the present amendment, Claims 2, 4-6, 25, and 26 have been amended. Claim 2 has been amended to recite a specific amount range of dispersant in the composition. Support for such amendment may be found on pg. 7, lines 26-27 of the specification as originally filed. Claims 4-6, and 25 have been amended to recite structural limitations to the type of carrier used in the compositions. Support for such amendments may be found in the originally filed specification in the following locations: pg. 8, lines 8-13; pg. 10, lines 17-22; pg. 11, lines 10-20; and pg. 12, lines 5-9. Claim 26 has been amended to specify that the composition is a solid, gel, or cream. Support for such amendment may be found on pg. 11, lines 10-20 of the specification as originally filed. Accordingly, Applicants respectfully submit that no new matter is added by these amendments. Furthermore, such amendments are made without conceding the correctness of the present rejections and without prejudice to Applicants' right to pursue relinquished subject matter in a future patent application. The Applicants specifically consider such amendment to place claims in better condition for allowance or appeal and therefore respectfully requests such amendment should be entered.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 2, 4-6, 25, and 26 as allegedly indefinite. The Examiner asserted that the terms "skin cleanser", "deodorant", "dental filling", and "lotion" render the claims vague and indefinite by not setting forth the required components of each composition. Applicants respectfully submit that the present

Serial No. 10/814,660
Docket No. 00802-22708

7

amendments to Claims 2, 4-6, 25 and 26, to include what the Applicants' expect would be viewed by the Examiner as structural limitations, obviate this rejection. The Applicants, therefore, respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1-13 and 15-27 as allegedly unpatentable over Davies in view of Raty. Additionally, the Examiner has rejected Claim 14 as allegedly unpatentable over Davies and Raty further in view of Flick. Applicants respectfully submit that these claims are patentable over the cited references for the reasons set forth below, and that the rejection should be withdrawn.

Before discussing the obviousness rejections herein, it is thought proper to briefly state what is required to sustain such a rejection. The issue under § 103 is whether the PTO has stated a case of *prima facie* obviousness. According to the MPEP § 2142, the Examiner has the burden and must establish a case of *prima facie* obviousness by showing the prior art reference, or references combined, teach or suggest all the claim limitations in the instant application. Further, the Examiner has to establish some motivation or suggestion to combine and/or modify the references, where the motivation must arise from the references themselves, or the knowledge generally available to one of ordinary skill in the art.

More specifically, in order to maintain a *prima facie* case of obviousness by combining references, the prior art must provide some reason or motivation to make the claimed compositions. *In re Dillon*, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990). As aptly stated in *In re Jones*, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992):

"Before the PTO may combine the disclosure of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art... Conspicuously missing from this record is any *evidence*, other than the PTO's speculation (if it be called evidence) that one of ordinary skill in the...art would have been motivated to make the modifications of the prior art necessary to arrive at the claimed (invention)."

With the above background in mind, Applicants respectfully submit that the Examiner has not satisfied the requirement for establishing a case of *prima facie* obviousness in any of the rejections. The Examiner has failed to show that the cited

Serial No. 10/814,660
Docket No. 00802-22708

8

references provide sufficient teachings or motivation to combine in order to arrive at Applicants' invention. Further, Applicants contend that the combination of references is based on hindsight. Therefore, without knowledge of the disclosure of the present invention, one of ordinary skill in the art would not be able to make the combinations proposed to arrive at the claimed invention. Additionally, even if the references were combined, the resulting combination fails to teach all of the claim limitations.

The Present Invention

The present invention as recited in independent Claim 1, provides for a remedial healthcare nanodiamond composition having a biologically acceptable carrier and a plurality of nanodiamond particles. The nanodiamond particles are dispersed in the carrier with a dispersant. Additionally, the nanodiamond particles have an average size of from about 0.5 nm to about 50 nm.

Likewise, independent Claim 10 is drawn to a cosmetic nanodiamond composition having a cosmetically acceptable carrier and a plurality of nanodiamond particles. As with the remedial healthcare nanodiamond composition, the nanodiamond particles have an average size of from about 0.5 nm to about 50 nm, and are dispersed in the carrier with a dispersant.

As noted above, independent Claim 19 is drawn towards a method of binding biological molecules, which requires formulating a nanodiamond composition having a plurality of nanodiamond particles dispersed in a biologically acceptable carrier. Additionally, the method includes contacting a biological material with the nanodiamond composition so that at least a portion of the biological material becomes bonded to the nanodiamond composition.

The Davies Reference

As stated above, the Examiner has rejected all pending claims, except Claim 14, based on Davies in view of Raty, and Claim 14 based on Davies and Raty further in view of Flick. Davies teaches the incorporation of diamond particles in nail varnishes and polishes. The reference teaches that nail varnishes and polishes including diamond particles provide nails with particularly wear-resistant coating, and that the included diamond may add sparkle. Davies notes that one of the main problems with incorporating diamonds in these compositions is the difficulty of keeping the particles in suspension. To deal with this problem, Davies teaches altering the liquid base of the composition (by adding colloidal silica) to a Bingham

Serial No. 10/814,660
Docket No. 00802-22708

9

plastic with a yield stress of not less than 0.2 Pa. Davies does not mention or infer other means of maintaining the diamonds in suspension. The diamonds Davies uses generally have a particle size of less than 30 microns, and typically in the 6 to 12 micron range (i.e. 6,000 to 12,000 nm range).

The Raty Reference

The Examiner admits that Davies fails to teach diamond particles having the recited particle range, and points to Raty to provide that aspect of the claimed invention. As discussed previously, Raty discloses "potential technological applications" including ultrananocrystalline diamond films for support of biological molecules. Raty discusses certain nanodiamonds, called "ultradispersed diamond" or UDD, "because of their very narrow size distribution." The reference further notes that spheroidal diamond nanoparticles with a size about 4 nm are commercially available. Raty also teaches that certain conditions for the creation of nanodiamonds can generate UNCD films, or "ultrananocrystalline diamond" films, and that such films might be used to "support" biological molecules and therefore allow for the creation of devices which integrate the biological molecules with electronic circuitry.

Lack of motivation to combine Davies and Raty

There is no motivation to combine the references Davies and Raty. The Examiner erroneously argues that because (1) Davies discusses the problem of suspending the particles in the liquid base and (2) Raty teaches nanodiamonds with ultradispersity, there would be a reasonable expectation of success by combining the teachings.

The error in this reasoning is most apparent in the Examiner's misreading of "ultradispersity" as used in Raty. The Examiner cites the portion of the article that notes that "nanodiamonds are often called 'ultradispersed diamond' (UDD) because of their very narrow size distribution" as motivation. While that statement alone clearly indicates that the dispersity of interest is the range of sizes of the nanodiamonds. The Examiner erroneously interprets the term 'ultradispersed diamond' to be indicative of the nanodiamond properties of suspension in solution.

In fact, the context of the article, and the use of the term "ultradispersity" makes it clear that the only "dispersity" discussed or even considered is in relation to the range of sizes of nanodiamond, in particular a very narrow distribution of nanodiamonds near 3 nm in size. For example, "[r]emarkably, the size distribution of

Serial No. 10/814,660
Docket No. 00802-22708

10

diamond nanoparticles seems to be peaked around 2-5 nm" (p. 792, 1st para.); "[o]ur findings provide an explanation of the size distribution" (p. 792, 1st para.); "a remarkable feature of extraterrestrial nanodiamonds is their narrow size distribution: those found in meteorites have a log-normal size distribution, with a median diameter of 2.6 nm ..." (p. 793, 1st partial para.). Indeed, the crux of the paper hinges on the comparison of the similarly-unique size distribution properties of both extraterrestrial nanodiamonds and synthetically-created nanodiamonds: "... there is no explanation of why nanodiamonds produced in space and on the Earth under very different conditions of atmosphere, temperature and pressure turn out to have similar size distributions, between 2 and 5 nm." (p. 793, 4th full para.). Further, the authors claim that the reason for the unique size distribution is that, according to their results, "as the size of diamond is reduced to about 3 nm, it is energetically more favorable for this material to have bare, reconstructed surfaces than hydrogenated surfaces." (p. 793, 5th para.). Finally, the paper concludes by stating, "we have proposed an explanation for the ultradispersivity of diamond at the nanoscale, which relies on simple thermodynamic arguments" and further that, "[w]e have shown that depending on [elements of the] growth process, diamond will grow into nanoparticles with reconstructed, non-hydrogenated surfaces of about 3 nm or into microcrystallites..." (p. 795, 3rd full para.).

Clearly, Raty's article, *Ultradispersivity of Diamond at the Nanoscale*, uses the term "dispersivity" according to the statistical definition, which is in reference to the degree of scatter of data. The Examiner, however, erroneously assumes that "dispersivity" is used according to the chemical definition used with disperse systems indicating particles suspended in a solid, liquid, or gas. While both uses are proper, they are certainly not interchangeable and can be used to indicate very different properties. Raty does not discuss dispersivity in the context of suspending particles in a solid, liquid, or gas. As such, it does not teach nanodiamond particles having a propensity for superior suspension properties. Therefore, there would be no motivation to combine the references based on the dispersibility properties of nanodiamond as presented in Raty.

Motivation to combine is not found in Davies. While Davies does note that there is a problem with suspending diamond particles in the liquid base, Davies does not state or infer that addition of a substance, like a dispersant, would be beneficial to

Serial No. 10/814,660
Docket No. 00802-22708

11

the suspension. Rather, Davies directly alters the properties of the liquid base. The proposed solution to the diamond suspension problem in Davies clearly demonstrates methodologies of directly altering the properties of the solution. Davies does not suggest in any manner that an alternate method of keeping diamond particles in suspension would be the use of an additional substance, like a dispersant. Davies, therefore, does not provide motivation to combine with Raty.

Furthermore, Raty does not provide any suggestion or inference that would motivate one of ordinary skill to combine the nanodiamonds of Raty with the compositions of Davies. In response to the Office Action dated July 3, 2006, Applicants noted that Raty mentions using ultrananocrystalline diamond films to support biological molecules, however films by their very nature are not dispersible as are particles. By the present Office Action, the Examiner agrees that the ultrananocrystalline diamond film is not the ultradispersed diamond taught in Raty. However, the Examiner continues to respond in the present Office Action by noting that Raty teaches spheroidal diamond nanoparticles of about 4 nm are commercially available and further, that a skilled artisan would be motivated to combine Raty and Davies "in expectation of obtaining a nail polish comprising nanodiamond particles which are stably dispersed in the composition." At best, the Examiner's position is that nanodiamonds are commercially available. However, the availability of the nanodiamonds is a far cry from providing motivation and is much closer to the speculation discussed in *In re Jones*. By the above-noted statement, the Examiner has made it clear that the misinterpretation of the Raty article continues to be the basis for combining the references.

Such misinterpretation of the article would not lead one of ordinary skill in the art, having the wherewithal to correctly interpret the "ultradispersity" discussed in Raty, to combine the nanodiamond particles with the composition of Davies. The Applicants' respectfully submit that the Examiner has failed to provide a suggestion or motivation to combine the references, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Therefore, a *prima facie* case of obviousness is lacking and Applicants respectfully request that the rejections be withdrawn.

Improper Hindsight by the combination of Davies and Raty

Serial No. 10/814,660
Docket No. 00802-22708

12

In addition to not establishing a case of *prima facie* obviousness, the Applicants respectfully assert the Examiner used improper hindsight to reconstruct the instantly claimed invention while using the Applicants' specification as a roadmap. The court has stated that the Applicants' specification cannot be the basis for motivation, i.e., no hindsight reconstruction. Yamonouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 56 U.S.P.Q.2d 1641 (Fed. Cir.), reh'g denied, 2000 U.S. App. LEXIS 34047 (2000). Accordingly, if a prior art reference is sought to provide a specific element of a claim with the use of hindsight, any rejection based thereon is improper and should be withdrawn.

By the mere fact that there is no motivation to combine substantiated in the references themselves, the logical conclusion is that the Examiner effectively used the Applicants' specification as a roadmap. The position is further strengthened by the statement in the present Office Action, in which the Examiner notes that Raty teaches "spheroidal diamond nanoparticles of about 4 nm is obtained and commercially available". It appears the Examiner was attempting to use Raty to establish that nanodiamond particles were available. Such availability is not disputed by the Applicants, however, the mere availability of nanodiamonds does not provide motivation to include the nanodiamonds in a composition such as taught in Davies. From the establishment of available nanodiamonds, the Examiner relies on impermissible hindsight to urge that a skilled artisan would use the nanodiamonds of Raty in the composition of Davies. As rejections based on the use of impermissible hindsight are improper, Applicants respectfully request that the rejection be withdrawn.

Lack of each and every element by the combination of Davies and Raty

Even if, *arguendo*, Davies and Raty are properly combined, the combination does not teach each and every element of the presently-claimed invention. Specifically, the inclusion of a dispersant with the diamonds in the carrier is not taught or suggested, or alternatively, the use of a carrier with diamonds and a dispersant is not taught or suggested. The addition of the colloidal silica in the Davies reference does not act as a "dispersant", but merely converts the liquid base to a Bingham plastic with a yield stress of not less than 0.2 Pa (i.e. changes the flowability properties of the liquid base). Neither Raty nor Davies teaches, infers or alludes to the inclusion of a dispersant within the carrier. Davies teaches altering the fluid

Serial No. 10/814,660
Docket No. 00802-22708

13

properties to affect the suspension of diamonds, and does not suggest adding a dispersant. Raty does not teach a fluid composition, and therefore cannot be interpreted to teach a dispersant.

The Examiner argues that the Bingham plastic meets the limitation "viscous biologically acceptable carrier" of instant claims 3 and 13. Claims 3 and 13, however, are directed to dispersants that may be used in the present compositions. If the Bingham plastic of Davies is used as the dispersant as the Examiner requests, it follows that Davies does not teach a carrier (biologically acceptable, cosmetically acceptable, or otherwise) as presently claimed. Therefore, Davies is devoid of teaching of either a carrier or a dispersant.

Additionally, the combination fails to teach the bonding of the biological material to the nanodiamond composition as required in Claim 19. To reiterate a previous point, with regards to biological materials, at most, Raty discloses supporting biological molecules with ultrananocrystalline diamond films. Applicants submit that the terms "supporting" and "bonding" describe distinctly different actions, and that the specifics and context of the Raty reference is insufficient to allow a reader to conclude that such terms could be interchangeable. Davies also fails to teach the bonding to a nanodiamond composition, for lack of a nanodiamond composition.

Davies in view of Raty, therefore, does not present a *prima facie* case of obviousness over the rejected claims. The combination fails for not presenting each and every element of the claims, for offering no motivation to combine the references, and for combining based on impermissible hindsight. Accordingly, Applicants respectfully submit that the rejection of the claims in view of Davies in view of Raty is improper and respectfully request that it be withdrawn.

Lack of each and every element in combination of Davies, Raty and Flick

The Examiner has rejected Claim 14 as being obvious over Davies and Raty as applied to Claims 1-13 and 15-27, and further in view of Flick. Flick was cited to provide the teaching of using stearylalkonium hectorite in nail lacquers. Flick does indeed teach using this chemical in nail lacquers, however, Flick does not remedy the inherent problems with the Davies-Raty combination as discussed above. Specifically, the combination does not teach a composition including nanodiamonds, a carrier and a dispersant, there is no motivation to combine, and such combination of

Serial No. 10/814,660
Docket No. 00802-22708

14

Raty and Davies is based on impermissible hindsight. Flick's addition of stearalkonium hectorite in nail lacquers does not teach the required compositional elements.

Lack of motivation to combine Davies, Raty and Flick

There is a lack of motivation to combine Flick with either reference. In addition to the aforementioned lack of motivation inherent with the Davies-Raty combination, Flick does not offer any motivation to combine with either reference. Flick merely shows a composition including a specific dispersant present in a nail lacquer. Although both Flick and Davies show nail lacquer compositions, Davies specifically teaches that the diamond particulates are suspended due to the manipulation of the carrier itself, not through addition of a dispersant. The alternate view, according to the Examiner, is that Davies teaches the Bingham plastic as the dispersant. Such composition, however, does not have a carrier, as presently claimed. Even if the combination of Davies and Flick were proper, there is still no motivation to combine with Raty for the reasons recited above.

Improper Hindsight by the combination of Davies, Raty, and Flick

As before, the combination of Davies with Raty is based on impermissible hindsight. Such impermissible hindsight is not remedied by the addition of Flick, as Flick merely introduces the use of stearalkonium hectorite in nail lacquers. The Examiner relies on impermissible hindsight to include the nanodiamonds of Raty in the composition of Davies (with or without the stearalkonium hectorite of Flick). As rejections based on the use of impermissible hindsight are improper, Applicants respectfully request that the rejection be withdrawn.

RECEIVED
CENTRAL FAX CENTER

Serial No. 10/814,660
Docket No. 00802-22708

FEB 26 2007

15

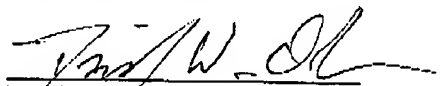
CONCLUSION

In view of the foregoing, Applicants believe that Claims 1-27 present allowable subject matter and allowance is respectfully requested. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney at (801) 566-6633 so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 26th day of February, 2007.

Respectfully submitted,



David W. Osborne
Attorney for Applicants
Registration No. 44,989

Of:

THORPE NORTH & WESTERN, LLP
8180 South 700 East, Suite 350
Sandy, Utah 84070
(801) 566-6633

DWO/SAA:tm